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Roche Group

Translation

Launch of the Anti-Cancer Agent / ALK Inhibitor "Alecensa®"

September 5, 2014 (Tokyo) – Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. Chairman & CEO: Osamu Nagayama (hereafter, "Chugai")] announced today that it has launched the ALK inhibitor "Alecensa® capsule 20mg and 40mg" [generic name: alectinib hydrochloride] (hereafter, Alecensa®) for the indication of "*ALK* fusion gene positive unresectable, recurrent / advanced non-small cell lung cancer" on September 5. Alecensa® received a manufacturing and marketing approval on July 4, 2014 and was listed on the National Health Insurance (NHI) reimbursement price list on September 2, 2014.

Alecensa® is a highly selective ALK inhibitor created at Chugai Kamakura Research Laboratories. Alecensa® exemplifies the Personalised Healthcare (PHC) Strategy promoted by Chugai and F. Hoffmann-La Roche Ltd. [Head Office: Basel, Switzerland. CEO: Severin Schwan] (hereafter, "Roche"). PHC is intended to determine the patients who are likely to respond to therapy by using diagnostic tools and/or biomarkers. PHC has the potential to deliver significant benefits in terms of therapeutic effects and health economics.

It has been reported that in 2 to 5 percent of patients with non-small cell lung cancer, a chromosomal rearrangement results in fusion of the *ALK* gene with another gene. ALK kinase signaling is constantly active in cells with such fusion genes, resulting in uncontrolled growth and transforming the cells into tumor cells. Alecensa® exerts its anti-tumor effect by selectively inhibiting ALK kinase activity, resulting in inhibition of tumor cell proliferation and induction of cell death.

The rights to Alecensa® in overseas countries including Europe and the US were out-licensed to Roche in 2012, and clinical trials of Alecensa® (Roche Development Code: RG7853) are currently ongoing in the US, Europe and other countries.

As the top pharmaceutical company in the field of oncology in Japan, Chugai will promote appropriate use so that Alecensa® can contribute optimally to the treatment of patients with "*ALK* fusion gene positive unresectable, recurrent / advanced non-small cell lung cancer" by providing a new therapeutic option.

Drug Information

Brand name:	Alecensa® Capsule 20mg	
	Alecensa® Capsule 40mg	
Generic name:	alectinib hydrochloride	
Indications:	*ALK* fusion gene-positive unresectable, recurrent or advanced non-small cell lung cancer (NSCLC)	
Dosage and administration:	The usual adult dosage is 300mg alectinib administered orally twice daily.	
Date of approval:	July 4, 2014	
Date of listing in the NHI reimbursement price:	September 2, 2014	
Date of launch:	September 5, 2014	
Shelf life:	Alecensa® Capsule 20mg	2 years and 6 months
	Alecensa® Capsule 40mg	2 years and 6 months
Drug price:	Alecensa® Capsule 20mg/capsule	901.70 yen
	Alecensa® Capsule 40mg/capsule	1,763.90 yen

About conditions for approval of Alecensa®

The conditions for approval were given as: "Alecensa® will be handled by doctors, medical institutions and pharmacists, who have sufficient experience in diagnosis and chemotherapy in lung cancer and who can appropriately control risks associated with Alecensa®; a drug use surveillance of all patients who receive Alecensa® should be conducted until the data of a certain number of patients are accumulated".

About the drug use surveillance of Alecensa® (All-case registration surveillance)

For the first 1,000 patients who receive Alecensa® treatment, data will be collected, analyzed and reported to the health authority. After collecting data for 1,000 cases, a review and decision will be made to determine whether a new surveillance or further safety measures should be considered. Results of this surveillance shall be reported to the public in future scientific meetings, as well as to the regulatory authorities.

Package photo